

WHAT IS CLAIMED IS:

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A multiple lumen access system for use in providing an entry port into the human body for selectively introducing medical devices therethrough and for providing auxiliary access into the body, the system including a multiple lumen access device comprising:

an outer tube which has a distal end for introduction into the body and a proximal end, the outer tube having a cross-sectional area;

a device lumen defined within the outer tube, the device lumen having a distal end and a proximal end, wherein medical devices may be passed through the device lumen;

at least one auxiliary lumen defined within the outer tube and separately from the device lumen, the auxiliary lumen having a distal end and a proximal end;

at least one flexible wall located within the outer tube having a distal end and a proximal end and opposite sides, wherein one side of the wall partly defines the device lumen and the other side of the wall partly defines the auxiliary lumen, the wall being sufficiently flexible to be movable from a relaxed position wherein the device lumen has a first cross-sectional area to flexed positions wherein the device lumen has cross-sectional areas which are greater than or less than the first cross-sectional area and less than the cross-sectional area of the outer tube.

2. The multiple lumen access system of claim 1 further comprising a device lumen valve adjacent the proximal end of the device lumen to provide sealing of the device lumen when medical devices are both present and absent from the device lumen.

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The multiple lumen access system of claim 1 further comprising one or more fluid reservoirs connected to one or more of the proximal ends of the auxiliary lumens.

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The first part of the paper is devoted to the study of the asymptotic behavior of the solutions of the system (1.1) as $\epsilon \rightarrow 0$. In the second part, we study the asymptotic behavior of the solutions of the system (1.1) as $\epsilon \rightarrow 0$. In the third part, we study the asymptotic behavior of the solutions of the system (1.1) as $\epsilon \rightarrow 0$.

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8. A multiple lumen access system according to claim 5 wherein the device lumen valve is molded separately from the junction housing of a material more rigid than the junction housing and is assembled with the multiple lumen access device by insertion in a cavity formed in the junction housing.

9. A multiple lumen access system according to claim 8 further including a device channel in the junction housing formed at an angle with the main channel and terminating at an internal end in fluid communication with the main channel, the device lumen valve being positioned in the cavity at an external end of the device channel so that medical devices may be inserted therethrough and enter the main channel at an angle.

Sub 137 10. A multiple lumen access system according to claim 9 wherein the main channel continues from the distal end of the junction housing past the device lumen to an opening in the junction housing enabling introduction of fluids therethrough to the main channel.

11. The multiple lumen access system of claim 5, wherein the device lumen valve has a contact face with at least one groove, and further comprising:

a contamination shield adapter having a contact face with at least one lug such that the lug mates with the groove when the adapter engages with the device lumen valve and provides a tactile feel to an operator when the adapter is properly engaged with the device lumen valve, the adapter being suitable for connecting a contamination shield to the device lumen valve.

12. A multiple lumen access system according to claim 4 wherein the main channel and auxiliary channel are oriented substantially coplanar so that the junction housing is substantially flat, and further including an extension tube extending from the proximal end of the junction housing and in fluid communication with the main channel wherein a device lumen valve is connected to the extension tube to therefore be in fluid communication with the main channel.

13. A multiple lumen access system according to claim 12 further including a side port in the device lumen valve enabling infusion of fluids to the extension tube and main channel.

14. A multiple lumen access system according to claim 12 further including mating threaded connectors between the device lumen valve and the extension tube enabling easy removal of the device lumen valve.

15. A multiple lumen access system according to claim 12 further including a second extension tube extending from the proximal end of the junction housing and in fluid communication with the auxiliary channel, and an auxiliary lumen valve connected to the second extension tube to therefore be in fluid communication with the auxiliary lumen.

16. The multiple lumen access system of claim 14 further comprising a luer connector on the device lumen valve and an infusion syringe having a mating luer connector.

Sub B 17. The multiple lumen access system of claim 1 wherein at least two auxiliary lumens are located within the outer tube of the multiple lumen access device.

18. The multiple lumen access system of claim 17 wherein the two auxiliary lumens are of different sizes.

19. The multiple lumen access system of claim 17 wherein one of the two auxiliary lumens is located between the other auxiliary lumen and the device lumen.

20. The multiple lumen access system of claim 17 wherein the distal ends of the two auxiliary lumens are located at different locations between the proximal and distal ends of the outer tube.

Sub B 21. The multiple lumen access system of claim 1 wherein the auxiliary lumen has a maximum cross-section formed when the flexible wall is flexed away from the auxiliary lumen as far as possible, and the device further includes an outlet for the auxiliary lumen formed in

the outer tube, the outlet having an area that is greater than or equal to the maximum auxiliary lumen cross-section.

22. The multiple lumen access system of claim 1 wherein the flexible wall forms an inner tube within the outer tube.

23. The multiple lumen access system of claim 22 wherein there are two inner walls forming the inner tube, the inner tube having a distal end and a proximal end and an exterior surface and an interior surface, wherein the interior surface defines the device lumen, and wherein two of the auxiliary lumens are located between the exterior surface of the inner tube and an interior surface of the outer tube.

24. The multiple lumen access system of claim 23 wherein the inner tube is connected to the interior surface of the outer tube at two locations to delineate the two auxiliary lumens.

25. The multiple lumen access system of claim 1 wherein at least one spacer rib is located on an interior surface of the outer tube for maintaining a space between the outer tube and the flexible wall.

26. The multiple lumen access system of claim 1 wherein the outer tube is made from a different material than the at least one flexible wall.

27. The multiple lumen access system of claim 1 further comprising a medical device located within the device lumen.

28. The multiple lumen access system of claim 1 wherein the flexible wall is constructed from a material and with a shape that moves from the relaxed position toward the flexed positions upon a pressure differential between the auxiliary lumen and the device lumen,

the movement being toward the device lumen, and wherein a displacement response curve of the flexible wall is non-linear such that the wall resists substantial movement from small pressure differentials.

29. The multiple lumen access system of claim 28 wherein the flexible wall has a variable thickness with areas of weakness in bending created at thinner portions so that when a device is present in the device lumen the wall contacts the device substantially along a line of contact to facilitate sliding of the device within the device lumen.

Sub B11 30. A multiple lumen access system for use in providing an entry port into the human body for selectively introducing medical devices therethrough and for providing auxiliary access into the body, the system including a multiple lumen access device comprising:

a sheath defining within a device lumen having a distal end and a proximal end, wherein medical devices may be passed through the device lumen, and at least one auxiliary lumen having a distal end and a proximal end;

a proximal junction housing made of a soft, flexible material having a proximal end and a distal end to which the proximal end of the sheath connects, the junction housing including a main channel in fluid communication with the device lumen and an auxiliary channel in fluid communication with the auxiliary lumen, the main channel and auxiliary channel diverging from the outer tube to be non-intersecting in the junction housing, the junction housing further defining a cavity on the proximal end in fluid communication with the main channel.

31. A multiple lumen access system according to claim 30 further including a device lumen valve attached to the junction housing so as to be in fluid communication with the device lumen of the sheath.

32. A multiple lumen access system according to claim 31 wherein the device lumen valve is molded separately from the junction housing of a material more rigid than the junction housing and assembled with the multiple lumen access device by insertion in the cavity formed in the junction housing.

Sub B12 33. A multiple lumen access system according to claim 31 further including a device channel in the junction housing formed at an angle with the main channel and terminating at an internal end in fluid communication with the main channel, the device lumen valve being positioned in the cavity at an outermost end of the device channel so that medical devices may be inserted therethrough and enter the main channel at an angle.

34. A multiple lumen access system according to claim 31 wherein the device lumen valve comprises a multi-component valve insert with a two-part rigid outer housing and at least one elastomeric inner valve member within the housing.

35. A multiple lumen access system according to claim 34 wherein the two-part rigid outer housing includes a portion forming an outermost opening and having internal threads for coupling with adapters for introducing medical devices.

36. A multiple lumen access system according to claim 34 including an elastomeric duckbill valve and an elastomeric wiper gasket within the housing.

Sub B3 37. A multiple lumen access system according to claim 30 further including at least one flexible wall located within the sheath and having a distal end and a proximal end and opposite sides, wherein one side of the wall partly defines the device lumen and the other side of the wall partly defines the auxiliary lumen, the wall being sufficiently flexible to be movable from a relaxed position wherein the device lumen has a first cross-sectional area to flexed positions wherein the device lumen has cross-sectional areas which are greater than or less than the first cross-sectional area and less than the cross-sectional area of the sheath.

38. A multiple lumen access system according to claim 30 wherein the sheath is a generally cylindrical solid member and the device lumen and auxiliary lumen are formed as longitudinal bores through the solid member.

39. A multiple lumen access device for use in providing an entry port into a human body for selectively introducing medical implements therethrough and for providing simultaneous auxiliary access into the body, the multiple lumen access device comprising:

a multi-lumen sheath having a proximal end and a distal end;

a junction housing having a proximal end and a distal end coupled to the proximal end of the multi-lumen sheath, the junction housing including a main channel in fluid communication with the one of the sheath lumens and an auxiliary channel in fluid communication with another of the sheath lumens; and

a strain relief insert formed of a soft, bendable material overmolded onto the sheath and having a proximal end coupled to the distal end of the junction housing, the strain relief insert capable of flexing to prevent the multi-lumen sheath from kinking at the sheath/junction housing coupling.

40. The multiple lumen access device of claim 39 wherein the strain relief insert is tapered with a wide portion connecting to the junction housing and a narrow portion being overmolded onto the sheath.

41. A multiple lumen access device comprising:

a junction housing having a proximal end and a distal end, the junction housing including a main channel and at least one auxiliary channel separate from the main channel, both the main channel and the at least one auxiliary channel extending from the proximal to the distal end of the junction housing;

a single lumen catheter having a proximal end and a distal end, the single lumen catheter including a hub connected to the proximal end;

a multi-function adapter having a first unit and a complementary second unit for coupling the junction housing to the single lumen catheter, a proximal end of the second unit being fixedly attached to the distal end of the junction housing, and a distal end of the first unit fixedly attached to the proximal end of the hub; and

the first unit being removably connected to the second unit such that the single lumen catheter is converted to a multiple lumen access device by virtue of the main channel and the at least one auxiliary channel in the junction housing.

42. The access device of claim 41 wherein the main channel and auxiliary channel diverge from the distal end of the junction housing to the proximal end of the junction housing.

43. The access device of claim 41 wherein the second unit includes at least one slot, and the first unit includes a lug extending radially outwardly and engaging with the slot.

44. The access device of claim 41 wherein the junction housing receives a valve insert having a device valve therein, the valve insert being positioned so that the device valve provides a seal around devices passed into the main channel.

45. The access device of claim 41 further including a small diameter catheter tube connected to the auxiliary channel of the multi-function adapter, the small catheter tube forming an infusion lumen while a space between the small catheter tube and the single lumen catheter defines a device lumen.

46. The multiple lumen catheter device of claim 45 wherein the junction housing includes a valve insert having a device valve therein, the valve insert being positioned so that the device valve provides a seal around devices passed into the main channel.

47. A multiple lumen catheter device comprising:

a multi-lumen catheter having a main lumen tube and at least one side lumen tube, the side lumen tube connected in a side-by-side fashion with the main lumen tube and being peelable from the main lumen tube to form sidearms; and

a hub connected to a distal end of each said main lumen tube and side lumen tube for fluid delivery or passage of a medical device therethrough.

48. The multiple lumen catheter device of claim 47 further comprising a sleeve disposed at a region where the main lumen tube and side lumen tube branch outwardly, the sleeve providing a cylindrical sealing surface against an entrance puncture in the skin of a patient.

49. The multiple lumen catheter device of claim 47 further comprising a junction housing connected to a proximal end of the main lumen tube, the junction housing being overmolded onto the main lumen tube and side lumen tube to limit the region in which the side lumen tube is peelable from the main lumen tube to a region proximal from the junction housing.

50. A multiple lumen access device, comprising:

a tubular single lumen sheath having proximal and distal ends, at least one infusion port being provided on the proximal end of the sheath; and

an elongated implement sized to fit coaxially within the single lumen sheath and form multiple independent lumens therein, at least one of the lumens being in fluid communication with the infusion port.

51. The multiple lumen access device of claim 50 wherein the single lumen sheath comprises a first introducer having a valve associated with its lumen, and the elongated implement comprises a second introducer having a valve associated with its lumen

and sized to fit coaxially within the first introducer sheath to thereby form multiple independent valved lumens.

52. The multiple lumen access device of claim 51 wherein each of the introducers includes a hub having a connection site to connect said at least two single lumen introducers.

53. The multiple lumen access device of claim 51 wherein said second introducer sized to fit coaxially within the first introducer sheath is made from a sufficiently flexible material so that at least one independent lumen formed by said coaxially fitted introducers has flexible walls defined by the flexible material and movable from a relaxed position wherein said at least one independent lumen has a first cross-sectional area, to flexed positions wherein said lumen has cross-sectional areas which are greater than or less than the first cross-sectional area.

54. The multiple lumen access device of claim 50 wherein said elongated implement comprises a plurality of ribs extending radially outward and the single lumen sheath has an inner wall and wherein said ribs contact the inner wall of the single lumen sheath to form the multiple independent lumens when said elongated implement is coaxially inserted within said single lumen sheath.

55. The multiple lumen access device of claim 54 wherein said elongated implement further has a tube about which the ribs project, the tube defining a further lumen.

56. The multiple lumen access device of claim 50 further comprising:
a hub on the single lumen sheath housing enclosing a hemostasis valve;
wherein the elongated implement fits through the hemostasis valve and into the single lumen sheath so that the ribs contact the inner wall of the single lumen sheath to form a plurality of auxiliary lumens.

57. The multiple lumen access device of claim 56 wherein a liquid tight seal is formed at an interface between the ribs and the inner wall of the single lumen sheath.

58. A multiple lumen access device according to claim 56 wherein the elongated implement includes a hub connected to a proximal end, and wherein the hub has two fluid access ports.

59. The multiple lumen access device of claim 56 wherein there are three auxiliary lumens formed by the ribs contacting with the inner wall of the single lumen sheath, and wherein there are three infusion ports connected to the single lumen sheath hub, each of the auxiliary lumens separately communicating with one of the infusion ports.

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B14 60. A method for selectively introducing medical devices into a human body through a single entry port and for providing simultaneous auxiliary fluid access into the body, comprising:

providing a multiple lumen access device comprising:

an elongated body which has a distal end for introduction into the body and a proximal end, the elongated body having a cross-sectional area;

a device lumen through which medical devices may be passed defined within the elongated body, the device lumen having a distal end and a proximal end;

at least one auxiliary lumen defined within the outer tube and separately from the device lumen, the auxiliary lumen having a distal end and a proximal end; and

at least one flexible wall located within the outer tube having a distal end and a proximal end and opposite sides, wherein one side of the wall partly defines the device lumen and the other side of the wall partly defines the auxiliary lumen, the wall being sufficiently flexible to be movable from a relaxed position wherein the device lumen has a first cross-sectional area to flexed positions wherein the device lumen has cross-sectional areas which are greater than or less than the first cross-sectional area and less than the cross-sectional area of the outer tube;

introducing the multiple lumen access device into the body with the distal ends of the device lumen and the auxiliary lumen being positioned within a vasculature of the human body; and

flowing a medical solution through the auxiliary lumen into the vasculature in the absence of a device in the device lumen to move the flexible wall from the relaxed position to a flexed position.

61. The method of claim 60 further comprising:

inserting a medical device through the device lumen into the vasculature; and
flowing a medical solution through the auxiliary lumen into the vasculature with a device present in the device lumen.

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62. The method of claim 60 further comprising the step of providing the multiple lumen access device with one or more fluid reservoirs connected to one or more of the proximal ends of the auxiliary lumens.

63. The method of claim 60 further comprising the step of providing the multiple lumen access device with a device lumen valve adjacent the proximal end of the device lumen to provide sealing of the device lumen when medical devices are both present and absent from the device lumen.

64. The method of claim 62 further comprising the step of providing the multiple lumen access device with a junction housing having a proximal end and a distal end to which the proximal end of the elongated body connects, the junction housing including a main channel in fluid communication with the device lumen and at least one auxiliary channel in fluid communication with the at least one auxiliary lumen, the main channel and auxiliary channel diverging from the elongated body to be non-intersecting in the junction housing.

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71. The method of claim 64 wherein the main channel and auxiliary channel are oriented substantially coplanar so that the junction housing is substantially flat, and further including an extension tube extending from the proximal end of the junction housing and in fluid communication with the main channel wherein the device lumen valve is connected to the extension tube to therefore be in fluid communication with the main channel.

72. The method of claim 71 further comprising the step of providing the multiple lumen access device with a side port in the device lumen valve enabling infusion of fluids to the extension tube and main channel.

73. The method of claim 71 further comprising the step of providing the multiple lumen access device with mating threaded connectors between the device lumen valve and the extension tube enabling easy removal of the device lumen valve.

74. The method of claim 73 further comprising the step of providing the multiple lumen access device with a luer connector on the device lumen valve and an infusion syringe having a mating luer connector.

Sub B18 75. The method of claim 71 wherein at least two auxiliary lumens are located within the elongated body of the multiple lumen access device.

76. The method of claim 75 wherein the distal ends of the two auxiliary lumens are located at different locations between the proximal and distal ends of the elongated body.

77. The method of claim 60 further comprising the steps of providing the multiple lumen access device with an inner tube formed by two flexible walls located within the elongated body, the inner tube having a distal end and a proximal end, and the inner tube having an exterior surface and an interior surface wherein the interior surface defines the

device lumen, and two auxiliary lumens located between the exterior surface of the inner tube and an interior surface of the elongated body.

78. The method of claim 77 wherein the inner tube is connected to the interior surface of the elongated body at two locations to delineate the two auxiliary lumens.

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BA 79. The method of claim 60 wherein the elongated body is made from a different material than the at least one flexible wall.

80. The method of claim 60 further comprising the steps of:
providing a device lumen valve adjacent the proximal end of the device lumen to provide sealing of the device lumen when medical devices are both present and absent from the device lumen, the device lumen valve having a contact face with at least one groove;

providing an adapter having a contact face with at least one lug such that the lug mates with the groove when the adapter engages with the device lumen valve and provides a tactile feel to an operator when the adapter is properly engaged with the device lumen valve; and

connecting a contamination shield to the adapter.

81. A method for selectively introducing medical devices into a human body through a single entry port and for providing simultaneous auxiliary fluid access into the body, comprising:

providing a tubular single lumen sheath having proximal and distal ends, at least one infusion port being provided on the proximal end of the sheath;

providing an elongated implement sized to fit coaxially within the single lumen sheath, at least one of the lumens being in fluid communication with the infusion port;

